Missouri Board of Pharmacy
March 4, 2003
SPECIAL MEETING
OPEN SESSION
Division of Professional Registration
Main Conference Room
Jefferson City, MO

The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. To better track the order in which items were taken up on the agenda, each item in the minutes will be listed in the order it was discussed at the meeting. The special meeting was called to order by President Michel at 11:10 a.m. on March 4, 2003.

Board Members Present
Martin H. Michel, R. Ph., President
Elaina Wolzak, R. Ph., Vice-President
Barbara Dunning, R. Ph., Member
Timothy Koch, R. Ph., Member
Doug Lang, R. Ph., Member
Gary Sobocinski, R. Ph., Member
Anita Parran, Public Member

Staff Present
Kevin E. Kinkade, R. Ph., Executive Director
Tom Glenski, R. Ph., Chief Inspector
Sharon L. Roberts, Executive Assistant

Others Present
Ron Smith, Assistant Attorney General
Bert McClary, BNDD

#1 **4 CSR 220-2.200 Sterile Pharmaceuticals** – Kevin Kinkade reported that the Board needed to review the general comments to this rule and the fiscal note. He noted that at the February meeting, the Board requested that the ASHP definition of Risk Levels 1, 2 and 3 be used in this regulation and that was inserted in section (1) (AA). It was Board consensus to approve this language.

One general comment on Section (11) stated the changes to this rule would impose a major constraint on practice. After discussion, it was board consensus that the changes already made to Section (11) addressed this issue. In addition, the change of the term “expiration date” to “beyond use date” also addressed this comment.

In his written comments, Eric Everett stated that in USP and ASHP references the theory for testing is the same. A test that reveals a problem calls for a shorter interval between tests and/or more samples, until the problem is identified or corrected. Conversely, tests with negative or acceptable results lengthen the time/sample interval. In other words, it can be assumed a historical database of successful test results validates personnel, equipment, components and techniques for the procedures done before the testing.

Discussion was held and it was Board consensus that these concerns were addressed in the changes made to Section (12)

Great Oak Pharmacy's general comment was that many of the requirements of this rule would only be feasible in a large hospital or large batch compounding entity and would send sterile compounding business out of the state.

Discussion was held and it was felt that the changes made throughout the rule addressed these comments. In addition, the out of state pharmacies who ship into Missouri would have to abide by Missouri regulations.

IACP's comments stated that the entire approach was fundamentally flawed and the Board had used an over-reliance on product testing and suggested the Board should consider an alternate approach. After discussion, it was Board consensus that the issues had been addressed and covered in the policy and procedure section, as well as the changes made to Section (12) regarding the testing issue.

It was further Board consensus that the Board Staff should develop a packet of information about sterile compounding and make it available to those who might inquire. In addition, inspectors should educate the pharmacists during the normal inspection process.

IACP also commented that the Board should make a provision in the final draft to allow pharmacies time to come into compliance with the provisions of this rule. It was noted that the effective date set by the Board will need to be both on the recission of the existing rule and the new rule. Discussion of this comment was held and the Board agreed that pharmacies needed sufficient time to comply with the rule.

Doug Lang made a motion to include an effective date of 12 months from the date of publication of the final order of rulemaking, on both the recission of the existing rule and the enactment of the new rule. Seconded by Barbara Dunning. Motion passed 6:0.

NCPA commented that the Robert Courtney case was the basis for the changes to this rule and that these changes fail to meet the objective. The comment also implied that Senator Bond had intervened and further implied that one or more board members may have been motivated by anti-competitive objectives in developing this rule that would

eliminate small business competitors from the Missouri marketplace. They also commented that the language regarding "making specific claims about compounded products" was a violation of free speech.

Kevin Kinkade stated he was planning to respond specifically to NCPA regarding their comments which went outside the rulemaking process.

It was noted that the Courtney case was not the only case the Board has reviewed involving compounding issues.

Harvey Tettlebaum, Husch and Eppenberger, commented that the enactment of this rule would result in patients going across state lines, that Missouri could lose 250 jobs; would increase the cost to the public; and would require compounding pharmacists to adhere to good manufacturing practices rather than pharmacy compounding practices. It was Board consensus that the comments had been addressed and Mr. Tettlebaum agreed.

Bert McClary pointed out that the term "NSF" has now officially been changed to NSF International. **Motion was made by Doug Lang to make this change in (1) (C), seconded by Elaina Wolzak. Motion passed 6:0.**

Fiscal Note – Discussion was held about the public and private fiscal note which was provided with the rule filing. A detailed review of each assumption used in the fiscal note was held. The term "expiration date" will be changed to "beyond use date" to reflect the changes made in the rule.

Discussion was held regarding the number of pharmacies used to calculate the fiscal note. It was suggested that Kevin Kinkade poll the inspectors to determine the number of pharmacies in their territory who would be involved in Risk Level 3 sterile compounding.

Statement #4 on the fiscal note was discussed at length and the Board made some changes to the fiscal note. Based on information provided by Inspector Tom Glenski, it was estimated that there may be 3 Risk Level 3 pharmacies in each territory, which would be a total of 18. Eighteen (18) pharmacies multiplied by 260 batches per year, would equal 4,600 batches, and this number was rounded up to 5,000 batches. It is estimated that 20% of these batches, or 1000, would require full testing and the remaining 4,000 would only be tested for sterility and pyrogenicity. It was Board consensus that these numbers be used in the fiscal note and changes will be made accordingly.

Because of the changes to the definition of Risk Levels, Risk Level 1 pharmacies will no longer have apparel requirements.

Doug Lang said once the rule is in place, then these organizations will need to do an assessment based on the definition in (AA) regarding the storage requirements of the medications to be administered and if, by choosing appropriate delivery device of those medications, theoretically they could remove themselves from Risk Level 2 to just a Risk Level 1, and not have the environmental requirements at all.

It was also determined that the inspection time should be increased to 2 hours for Risk Level 1 and 4 hours for Risk Level 2 and 3 and the costs for the refractors should be deleted.

Eric Everett commented on the pyrogen and potency testing, noting the batch issue. He said majority of sterile products are a single prescription for immediate use, and further stated that pyrogen and potency testing would add cost per batch. Doug Lang pointed out that a pharmacy could utilize an Isolator Box rather than be required to build a clean room.

IACP commented in general about higher costs and rationale used for assumptions, After discussion, it was Board consensus that the comments had been addressed by changes made to the rule and the fiscal note.

Gary Sobocinski made a motion to approve the fiscal note as amended , seconded by Doug Lang. Motion passed 6:0.

Elaina Wolzak made a motion to approve the final order of rulemaking for 4 CSR 220-2.200 Sterile Products, as amended. Seconded by Doug Lang.

The Board recessed for lunch at approximately 12:40, and reconvened at 1:45 p.m.

Eric Everett requested permission to offer specific comments to the sterile pharmaceutical rule. Mr. Everett expressed concerns about the emergency dispensing language. It was pointed out that the onus is on the prescriber when he is notified that the product is released prior to testing. After discussion, it was board consensus that no changes be made to the definition of emergency dispensing.

Mr. Everett expressed additional concerns about pyrogen and potency testing and he was reminded that the Board is only doing pyrogen testing on injectable products.

4 CSR 220-2.400 Compounding Standards of Practice- Kevin Kinkade reviewed the specific comments and discussion was held.

Bert McClary, BNDD, withdrew his original comment and submitted another comment dealing with the definition of compounding and repackaging. The Board reviewed his new comment. No changes were made to the rule based on this comment.

Section (1) - Kevin Kinkade summarized the comments to this section and a discussion was held.

Tom Glenski suggested that the word "prescription" be added in front the words "drug order" and delete the word "initiative".

Motion was made by Barbara Dunning and seconded by Elaina Wolzak, to make the changes as noted by adding the word "prescription" in front of the words "drug order" and delete the word "initiative". Motion passed 6:0

Section (2) -Kevin Kinkade summarized the comments to this section and a discussion was held.

IACP commented that the last sentence of section (2) should be stricken to eliminate potential conflict regarding the definition of manufacturing. NACDS commented that this language would prohibit Class J: Shared Services pharmacies from providing compounded drug products to other pharmacies, based on their Class J provisions. It was Board consensus that the language would not prohibit this activity for Class J pharmacies because this would be based on a specific prescription and is addressed in Section (1).

Gary Sobocinski made a motion to delete the last sentence in Section (2), beginning with "Manufacturing also" and ending with "practitioners or other persons" . Seconded by Doug Lang. Motion passed 6:0

Section (5) (F) – Kevin Kinkade summarized the comments to this section and a discussion was held.

Harvey Tettlebaum commented that the amendments seem to favor manufacturers and also felt that the restrictions on commercial free speech violated constitutional principles. The changes to (5) (F) are impractical and will increase the cost of liability insurance for pharmacists. The Compounding Lab also commented on this section alleging the requirement to list all therapeutic ingredients on the label was burdensome and virtually impossible. Discussion was held and the Board did not feel that the commentor presented specific evidence that this amendment favored manufacturers or violated free speech and thus did not agree with these comments. However, they did agree that the requirement to list all therapeutic ingredients on the label would be impractical and made a change to this section.

Doug Lang made a motion to change the word "label" to "container" in (5) (F), seconded by Anita Parran. Motion passed 6:0.

Section (6) (A) – Kevin Kinkade summarized the comments to this section and a discussion was held.

Comments on this section were from Bert McClary and IACP and both noted that the requirement in this section places the liability for proper preparation of manufactured drugs on the pharmacist, who has no direct contact with or control of manufacturers. Discussion was held.

Tim Koch made a motion to delete the sentence in (6) (A) starting with "These responsibilities" and ending with "prior to dispensing". Seconded by Gary Sobocinski. Motion passed 6:0

Section (5) (A) 8. – Tom Glenski pointed out some grammatical changes which need to be made to this section, so that this sentence reads:

"The identifying prescription number(s) or the readily retrievable unique indentifier(s) for which the compound was dispensed,.

Barbara Dunning made a motion to make the changes as Tom Glenski noted, seconded by Anita Parran. Motion passed 6:0

Tom Glenski also suggested that the term "batched compounded product" be used throughout the rule in the place of references to "bulk compounded product", "batched product", "excess product" and "excess compounded product". In addition, a definition of "batched compounded product" should be added as a new (3), to read as follows:

A batched compounded product is defined as a product compounded in advance of receipt of a prescription OR a product compounded in a supply that will be used on ore than one dispensing to a patient or patients OR any product compounded in excess of the filling of an individual prescription. A batch is defined to be a specific quantity of product compounded in a single, discrete process, by the same individuals, carried out during one (1) limited time period.

Barbara Dunning made a motion to make the changes as stated by Tom Glenski, seconded by Elaina Wolzak. Motion passed 6:0

Section (6) (A) 3.-

IACP commented that the term "on a routine basis" should be deleted from (6) (A) 2. ; and further that the 2nd and 3rd sentence in this section should be deleted because the requirements of this language put an undue burden on the pharmacist since these areas of out of his/her control.

Motion was made by Tim Koch to add the sentence "Drug components must meet compendium standards or the certificate of analysis must be on file when bulk drug substances are used", in Section (6) (A) 2. Seconded by Elaina Wolzak. Motion passed 6:

Motion was made by Gary Sobocinski that in (6) (A) 3., the words "There is assurance" and replace it with "Reasonable" seconded by Barbara Dunning. Motion passed 6:0.

The Compounding Lab commented on Section (6) (A) 5, noting that in a one-person operation, the ability to separate functions is not feasible. The Board agreed with this observation.
Motion was made by Elaina Wolzak to delete section (6) (A) 5, seconded by Barbara Dunning. Motion passed 6:0.

Section (6) (B) – Kevin Kinkade reported on a comment from MSHP that the word "reported" should be added in front of "infection rates" in order to clarify this sentence. It was also noted that the word "or complaint" in the last sentence should be deleted.

Doug Lang made a motion to make these changes in Section (6) (B), seconded by Gary Sobocinski. Motion passed 6:0.

Kevin Kinkade noted that there were no comments on the recall language in this amendment, but felt it needed to be addressed. After discussion, it was Board consensus to add a new Section (6) (C) setting out what constitutes a recall and how it should be handled by the pharmacy.

Section (7) - Kevin Kinkade reviewed the comments to this section.

Harvey Tettlebaum stated that this section falls outside the statutory authority of the Board of Pharmacy. IACP noted in their comment that this language potentially could interfere with physicians' ability to prescribe appropriate therapies for their patients and could create controversy between the two licensing boards. They felt that the presence of a prescription order for the specific compounded medication should fulfill the documentation requirement. It was also noted that the word "Federal" should be changed to "Food", when referring to the Food and Drug Administration (FDA).

After discussion, it was consensus of the Board to make the change from "Federal" to "Food". The Board did not agree with the other comments since the intent of the Board in this section is not to bar different dosage forms but to address the issue of making a commercially available product. In addition, the Board believes that the responsibility for regulating the practice of pharmacy clearly falls under the Board's statutory authority in Chapter 338.

Motion to Close 4.45 p.m.. on March 4 4, 2003.
Anita Parran made a motion that the board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this

closed meeting be closed under Section 610.021.14 (1), (3), (5), (7), (13) and (14) and under Section 620.010.14 (7). Seconded by Barbara Dunning. Motion passed 6:0 with roll call vote as follows:

Gary Sobocinski - Yes	**Elaina Wolzak - Yes**
Tim Koch – Yes	**Barbara Dunning - Yes**
Anita Parran – Yes	**Doug Lang – Yes**

Return to Open 5:05 p.m. March 4, 2003- On Motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at 5:05 p.m.

Motion was made by Tim Koch and seconded by Elaina Wolzak to add "The compounding of any drug product to be sold without a prescription is prohibited" to the end of Section (8). Motion passed 6:0.

Section (10) – Tom Glenski suggested that the reference to federal law should be removed. The Compounding Lab and IACP expressed concerns that requiring prior identification of a patient is over burdensome and pharmacies should be allowed to compound for specific office use by physicians in various procedures. Eric Everett discussed the need to be able to provide medications to physicians and dentists to use in a procedure; they do not always know whether or not a particular drug will be needed and so need to have it on hand and available.

Mr. Kinkade pointed out the FDA position on compounding only on a patient specific prescription. Suggestion was made that Board staff research this issue with other states to see how it is being handled and inform the Board of the results for review at a future board meeting.

Motion was made by Doug Lang and seconded by Elaina Wolzak to delete the phrase "In accordance with federal law" in Section (10). Motion passed 6:0.

Section (5) – Discussion was held regarding the term "expiration date".

Motion was made by Doug Lang to change the term "expiration date" to "beyond use date" everywhere it appears in the rule and in addition, to create a new Section (4) to provide a definition of "beyond use date" as follows:

Beyond Use Date: A date after which a compounded preparation should not be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their beyond-use dates must be assigned based on

criteria different from those applied to assigning expiration dates to manufactured drug products. Seconded by Elaina Wolzak. Motion passed 6:0.

Some entities commented that this amendment should have contained a fiscal note to reflect the costs to pharmacies to comply. After discussion, it was Board consensus that the changes made to the amendment addressed the cost issue and they did not believe that a fiscal note was needed.

Elaina Wolzak made a motion to approve the final order of rulemaking on 4 CSR 220-2.400, with the changes as approved and further, that the effective date of this amendment should follow the normal rulemaking cycle and become effective 30 days after publication in the *Missouri Register*. Seconded by Doug Lang. Motion passed 6:0.

Motion to Close 5:50 P.M. on March 4, 2003.

Doug Lang made a motion that the board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021.14 (1), (3), (5), (7), (13) and (14) and under Section 620.010.14 (7). Seconded by Barbara Dunning. Motion passed 6:0 with roll call vote as follows:

Gary Sobocinski - Yes	**Elaina Wolzak - Yes**
Tim Koch – Yes	**Barbara Dunning - Yes**
Anita Parran – Yes	**Doug Lang – Yes**

Return to Open 7:05 p.m. on March 4, 2003

Upon motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session.

Motion to Adjourn

At 7:06 p.m., Doug Lang made a motion to adjourn the meeting, seconded by Anita Parran. Motion passed 6:0

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KEVIN E. KINKADE, R. Ph.
EXECUTIVE DIRECTOR

DATE APPROVED:

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